



PRESS RELEASE

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Egetis Receives Conditional FDA Acceptance of Proprietary Name Emcitate®

Stockholm, Sweden, April 8, 2026. Egetis Therapeutics AB (publ) (“Egetis” or the “Company”) (NASDAQ Stockholm: EGTX), today announced that the U.S. Food and Drug Administration (FDA) has completed their review of the proposed proprietary name Emcitate and have concluded that it is conditionally acceptable. Final approval is reserved until the new drug application (NDA) is approved.

On March 27, 2026, Egetis announced that FDA has accepted the filing of its NDA for Emcitate® (tiratricol) for the treatment of MCT8 deficiency. The application has been granted Priority Review and assigned a Prescription Drug User Fee Act (PDUFA) target action date, or FDA decision date, of September 28, 2026.

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About Egetis Therapeutics

Egetis Therapeutics is an innovative and integrated pharmaceutical company, focusing on projects in late-stage development for commercialization for treatments of serious diseases with significant unmet medical needs in the orphan drug segment.

The Company's lead drug candidate Emcitate® (tiratricol) is developed for the treatment of patients with monocarboxylate transporter 8 (MCT8) deficiency, a highly debilitating rare disease with no available treatment. In February 2025 the European Commission approved Emcitate® as the first and only treatment for MCT8 deficiency in EU. Egetis initiated the launch of Emcitate® in Germany on May 1, 2025. Emcitate® (tiratricol) is not approved in the USA.

On March 27, 2026, Egetis announced that the U.S. Food and Drug Administration (FDA) has accepted the filing of its New Drug Application (NDA) for Emcitate® (tiratricol) for the treatment of MCT8 deficiency. The application has been granted Priority Review and assigned a Prescription Drug User Fee Act (PDUFA) target action date, or FDA decision date, of September 28, 2026.

The NDA for Emcitate® (tiratricol) for treatment of MCT8 deficiency is based on clinical data from Triac Trial I, Triac Trial II, ReTRIACt, EMC Cohort Study, EMC Survival Study and the US Expanded Access Program.

Tiratricol holds Orphan Drug Designation (ODD) for MCT8 deficiency and resistance to thyroid hormone beta (RTH-beta) in the US and the EU. MCT8 deficiency and RTH-beta are two distinct indications, with no overlap in patient populations. Tiratricol has been granted Breakthrough Therapy Designation and Rare Pediatric Disease Designation (RPDD) by the FDA, which gives Egetis the opportunity to receive a Priority Review Voucher (PRV) in the US, after approval.

The drug candidate Aladote® (calmangafodipir) is a first in class drug candidate developed to reduce the risk of acute liver injury associated with paracetamol (acetaminophen) overdose. A proof of principle study has been successfully completed. The design of a pivotal Phase IIb/III study (Albatross), with the purpose of applying for market approval in the US and Europe, has been finalized following interactions with the FDA, EMA and MHRA. The development program for Aladote® has been parked. Aladote® has been granted ODD in the US and in the EU.

Egetis Therapeutics is listed on the Nasdaq Stockholm main market (Nasdaq Stockholm: EGTX).

For more information, see www.egetis.com

Attachments

[Egetis Receives Conditional FDA Acceptance of Proprietary Name Emcitate®](#)